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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,665	06/12/2001	Douglas R. Daum	279.358US1	4223

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,665	DAUM, DOUGLAS R.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/14/04 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-17 and 19-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-17 and 19-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the Amendment file 6/14/04, the Applicant has amended the claims, hence the rejections of record are withdrawn and a new rejection established in the subsequent paragraph. Since the rejections rely on the same references, the Applicant's arguments are responded to as appropriate in association with the different rejections. A number of 35 U.S.C. 112 issues are noted below so the rejection reflects the Examiner's best understand of the claimed invention.

Claim Rejections - 35 USC § 112

2. Claims 1, 3-17 and 19-35 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As noted in the previous office action, the Examiner is unable to find in the specification disclosure of "net fluid shift" related to impedance detection in the thorax (claims 1, 17, 31). The Examiner does find "fluid shift" (specification – page 8, line 23). The Applicant arguments filed 6/14/04 have been fully considered but they are not convincing. The Applicant argues that one of ordinary skill in the art would understand that the electrode configurations taught by Hauck (US 5284136) and Hartley et al. (US 6075015) would inherently yield an indication of net fluid shift away from the thorax. The Examiner disagrees. Hauck and Hartley et al. use impedance measurements to monitor cardiac and respiratory activity, and are not concerned with

fluid shifts. The term "net fluid shift" can not be found in the specification or in any of the references incorporated in the specification by reference. The limitation of "net fluid shift" appears to be new matter and new matter may not be entered at this point in the prosecution.

The Examiner is unable to find in the specification disclosure the newly added limitations of "an exercise activity level" (claim 1), "patient exercise level" (claim 17) and "patient exercise activity level" sensor. The Examiner does find an "activity" sensor (specification – page 7, line 1). These limitations appear to be new matter and new matter may not be entered at this point in the prosecution.

3. Claims 1, 3-17 and 19-35 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner is unable to find in the specification "net fluid shift" away from the thorax, nor discussion of the apparatus and processes to support these limitations, hence it is unclear how this term is defined, what apparatus and method support determining this value, and how this value, the "net fluid shift", is relevant to this invention. Appropriate correction is required.

4. Claims 1, 3-17 and 19-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 5-6, "the thoracic impedance" lacks antecedent basis.

In claims 1, 17, and 31, the phrase "rate response factor mapping" is unclear. Review of the specification and figure 3 shows the rate responsive factors, lines 304 and 306, as linear entities representing a group of points, the points combining to create a "map". It appears the rate responsive factor is the map and does not do the "mapping". It also appears relative to the rate responsive factor represent by line 304, a single metabolic need is correlated to a signal pacing rate, rather than a range of metabolic needs being correlated to a range of pacing rates. Clarification is needed.

In claim 17, line 17, "the hypotension condition indicator" lacks antecedent basis.

In claim 31, line 3, "a thorax-impedance" is unclear.

In claim 31, line 16, "the hypotension condition indicator" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. Claims 1, 3-17 and 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US 6044297) in view of Pitts Crick et al. (US 6104949) and further in view of Hudrlik (US 5282840) and further in view of Combs et al. (US 5957861).

Sheldon et al. disclose an implantable stimulation device and teach a responsive hypotension detection detection indicator, to indicate both postural (col. 7 @ 28) and non-postural (col. 7 @ 44) hypotension, using activity sensors and heart rate sensors for the purpose of providing treatment to prevent the patient from fainting or feeling faint (col. 5@ 42-46; col. 6 @ 53-65; col. 7 @ 27-59; col. 9 @ 10-13). The activity sensors can define posture and activity

levels and both types of posture and activity signals can be used to affect the therapy by controlling the pacing rate delivered by the pacemaker (col. 1 @ 19-45). Sheldon et al. teach inclusion of blood pressure monitoring, read as monitoring of hypotension, to treat syncopal patients (col. 9 @ 10-13; col. 12 @ 10-31; col. 22 @ 4-9).

As to the stepping of rate responsive factor (claims 14-16 and 27-30), pacing therapy is taught as being stepped (col. 7 @ 31-34; col. 11 @ 63 – col. 12 @ 9). US 5354317 to Alt, incorporated by reference (col. 2 @ 51-53; col. 3 @ 7-17), discloses variable rate pacing to provide electrical output signals uniquely responsive to pre-selected positions, including gradual rate changes (Alt - abstract) to provide optimal pacing therapy for the subject's specific needs.

Sheldon et al. disclose the claimed invention except for using transthoracic impedance to indicate hypotension.

Postural hypotension (fluid moving to the patient's extremities and the patient being unable to compensate for this movement) and pulmonary edema (lungs filling with fluid and the patient being unable to compensate for this fluid collection) are recognized as conditions frequently associated with the later stages heart failure (Sheldon et al. – col. 7 @ 31-46; Pitts Crick et al. – col. 4 @ 48 – col. 5 @ 55; col. 5 @ 37-39; col. 6 @ 20-30). Both these conditions create changes in the fluid levels in the thoracic tissues as fluid is shifted away from the thorax in the hypotension condition and as fluid is shifted into the throrax in the edema condition, hence accurate monitoring of fluid changes in the trans-thoracic tissues can quantify

changes associated with the conditions of hypotension and pulmonary edema and can indicate the need for treatment (Sheldon et al. – col. 7 @ 31-46; col. 21 @ 62 – col. 22 @ 9; Pitts Crick et al. – abstract; col. 1 @ 38-45; col. 2 @ 35-40; col. 5 @ 34-39; col. 6 @ 20-30). Pitts Creek et al. teach the monitoring of fluid changes using the sensing of trans-thoracic impedance for the purpose of accurately monitoring the fluid level in the tissues, and correlating posture changes with impedance to diagnose and treat congestive heart failure.

In the 09/832,365 application that is incorporated by reference in the instant applcation, the Applicant states treatment of hypotension can be based on trans-thoracic impedance and one or more secondary variables such as an accelerator to detect posture changes (specification – page 10, lines 15-19), hence absent any teaching of criticality or unexpected results, merely changing the basis for treatment of hypotension from an impedance sensor to an impedance and activity sensors would have been an obvious design choice.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used trans-thoracic impedance sensors with posture sensors to monitor fluid changes in the Sheldon et al. system in order to utilize a proven means to measure shifts in thoracic fluids so automatic treatment is provided that rapidly responds to the early signs of fluid shifts in the thorax (col. 1 @ 40-46; col. 5 @ 34-39; col. 6 @ 20-30).

Modified Sheldon et al. disclose the claimed invention except for:

- the responsive hypotension indicator being responsive to thoracic impedance, indicating a fluid shift away form the thorax (claims 1 and 17),

- a respiration sensor used as a first sensor to define metabolic rate and to provide a base rate for pacing (claims 1 and 17), and
- a rate responsive factor, being adjusted in response to the hypotension condition indicator (the thoracic impedance signal), the rate responsive factor impacting the pacing rate (claims 1 and 17) and
- a rate responsive factor being a mapping of the correlation of the metabolic needs to pacing rate (claims 1, 17 and 31).

Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic, net shifts in the impedance (col. 2 @ 32-35). These fluid shifts are treated by increased pacing rates (col. 11 @ 30-43) for the purpose of assisting in shifting the fluid back to the thorax (col. 2 @ 32-39). Hudrlik teaches using throacic impedance (the responsive hypotension indicator), respiratory (first sensor) and activity monitors to define the pacing treatment in situations of fluid shifts (col. 3 @ 9-15). The pacing rate is established based on the first sensor (respiration sensor) and adjusted using a rate responsive factor (having an instantaneous and long-term component) that is based on the hypotension indicator (impedance sensor). These collection of ranges of pacing rates resulting from ranges of metabolic needs "map" possible conditions and treatment responses (col. 3 @ 9-27; col. 3 @ 59 – col. 4 @ 1; col. 6 @ 3-22; col. 10 @ 51 – col. 11 @ 18; col. 11 @ 30-43; col. 11 @ 55 – col. 12 @ 27; col. 12 @ 59-67). The impedance measurement includes a plurality of blood vessels (col. 4 @ 45-54). As discussed previously, hypotension is recognized as being associated with a fluid shift to

the extremities causing fainting or the feeling of being faint. The fluid shift associated with hypotension is read a significant reduction of blood flow in the thorax. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used thoracic impedance, respiratory and activity sensors to monitor fluid shifts and to increase the pacing rate as needed to shift fluid back to the thorax based on the first sensor and the rate responsive factor in the modified Sheldon et al. system in order to utilize proven monitoring and treatment system for fluid shifts so adequate fluid flow is provided to the thoracic tissue avoiding tissue damage (ischemia) and preventing patient injury from falls that might result if the patient faints (col. 2 @ 32-39).

Modified Sheldon et al. disclose the claimed invention except for the cutoff frequency for the fluid impedance signal being 0.01 to 0.5 Hz, or approximately 0.1 Hz or below about 0.5 Hz.

Combs et al. teach measure the impedance of fluid using a measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz, or below about for the purpose of removing cardiac and respiratory components from the impedance signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an impedance measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz in the modified Shelson et al. system in order to avoid extraneous noise in the fluid impedance signal so an accurate determination of the fluid level can be determined (col. 6 @ 58 – col. 7 @ 33).

The Applicant's arguments filed 6/14 04 have been fully considered, but they are not convincing.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Sheldon et al. teach an implanted device responsive to hypotension using activity and heart rate sensors. Pitts-Creek et al. is incorporated to teach transthorasic impedance to monitor fluid shifts. Hudrlik is incorporated to the teach the responsiveness of hypotension, fluid shift and impedance, a respiration sensor, and a rate responsive factor. Combs is incorporated to teach impedance monitoring ranges.

As to the Applicant's argument that Pitts Creek et al. monitors fluid shifts *away* from the throrax, it is reiterated that Pitts Creek et al is incorporated to teach the monitoring of fluid shifts using impedance, the direction of the shift is not view as being significant to the teaching.

As to the Applicant's argument of the frequency teachings of Hudrlik in figure 3 teaching away from the instant invention, the Examiner disagrees noting figure 3 teaches the change in normal versus ischemic tissue as quantified by the frequency associated with the impedance plot.

As to the Applicant disagreeing with the assertion that Hurdlik "teaches that gross tissue insults, created by a significant reduction of blood blow to tissue of the thorax, cause dramatic shifts in the impedance", the Examiner disagrees that this is an assertion, noting this is a direct quote from Hurdik (column 2, lines 32-35).

In response to the Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (noted in quotations) (i.e., the rate responsive factor is "a specific linear or non-linear" mapping "between" a range of a signal correlative to metabolic need and a range of the pacing rate) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant incorrectly assumes the Examiner relies on a single cited portion of the Hudrlik references to serve as the basis of the rejection, rather that the combination of all the cited portions of the Hudrlik reference as noted in the rejection of record.

6. Claims 1, 3-10, 13, 17, 19-26 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al. (US 5913879) in view of Standberg (EP 0 620 420 A1) and further in view of Hudrlik (US 5282840) and further in view of Combs et al. (US 5957861).

Ferek-Petric et al. teach an implantable therapy device that detects venous pooling (correlative to hypotension), read as detecting fluid shift away from the thorax, using a flow detector and provides therapy in response to the fluid shift (abstract; figure 2; col. 1 @ 7-11; col. 3 @ 17-63). Ferek-Petric et al. teach blood flow measurement can be made by impedance measurements (col. 2 @ 51-55) as taught by Strandberg using electrodes (col. 5 @ 11 – col. 6 @ 4).

Ferek-Petric et al. disclose the claimed invention except for:

- the responsive hypotension indicator being responsive to thoracic impedance, indicating a net shift in fluid shift away form the thorax across a plurality of vessels (claims 1 and 17) ,
- a respiration sensor used as a first sensor to define metabolic rate and to provide a base rate for pacing (claims 1 and 17),
- a rate responsive factor, being adjusted in response to the hypotension condition indicator (the thoracic impedance signal), the rate responsive factor impacting the pacing rate (claims 1 and 17),
- the rate responsive factor being a mapping of the correlation of the metabolic needs to pacing rate (claims 1, 17 and 31), and
- a sensor correlative to the subject's metabolic need (claims 1 and 17), the signal being a breathing signal (claims 8 and 24) or an accelerometer (claim 25).

Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic, net shifts in the impedance (col. 2 @ 32-35). These fluid shifts are treated by increased pacing rates (col. 11 @ 30-43) for the purpose of assisting in shifting the fluid back to the thorax (col. 2 @ 32-39). Hudrlik teaches thoracic impedance (the responsive hypotension indicator), respiratory (first sensor) and activity monitors are used to define the pacing treatment in situations of fluid shifts (col. 3 @ 9-15). The pacing is established based on the first sensor (respiration sensor) and adjusted using a rate responsive factor (have an instantaneous and long-

term component) based on the hypotension indicator (impedance sensor). These collection of ranges of pacing rates resulting from ranges of metabolic needs "map" possible conditions and treatment responses (col. 3 @ 9-27; col. 3 @ 59 – col. 4 @ 1; col. 6 @ 3-22; col. 10 @ 51 – col. 11 @ 18; col. 11 @ 30-43; col. 11 @ 55 – col. 12 @ 27; col. 12 @ 59-67). The impedance measurement includes a plurality of blood vessels (col. 4 @ 45-54). As discussed previously, hypotension is recognized as being associated with a fluid shift to the extremities causing fainting or the feeling of being faint. The fluid shift associated with hypotension is read a significant reduction of blood flow in the thorax. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used thoracic impedance, respiratory and activity sensors to monitor fluid shifts and to increase the pacing rate as needed to shift fluid back to the thorax based on the first sensor and the rate responsive factor in the modified Sheldon et al. system in order to utilize proven monitoring and treatment system for fluid shifts so adequate fluid flow is provided to the thoracic tissue avoiding tissue damage (ischemia) and preventing patient injury from falls that might result if the patient faints (col. 2 @ 32-39).

Modified Ferek-Petric et al. disclose the claimed invention except for the cutoff frequency for the fluid impedance signal being 0.01 to 0.5 Hz, or approximately 0.1 Hz to reflect baseline changes.

Combs et al. teach measure the impedance of fluid using a measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz for the purpose of removing cardiac and respiratory components from the impedance signal so baseline changes can be detected. It would have been

obvious to one having ordinary skill in the art at the time of the invention to have used an impedance measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz in the modified Ferek-Petric et al. system in order to avoid extraneous noise in the fluid impedance signal so an accurate determination of the fluid level can be determined (col. 6 @ 58 – col. 7 @ 33).

The Applicant's arguments filed 6/14 04 have been fully considered, but they are not convincing.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Ferek-Petric et al. teach an implanted device that monitors impedance and is responsive to responsive to fluid shifts (correlative to hypotension). Hudrlik is incorporated to the teach the responsiveness of hypotension/ fluid shift/ impedance, a respiration sensor, a rate responsive factor and a sensor correlative to the metabolic needs. Combs et al. is incorporated to teach impedance monitoring ranges.

Specification

7. The amendment filed 6/14/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the

original disclosure is as follows: The Examiner is unable to find in the specification of the detecting the thoracic impedance "net fluid shift" away from the thorax (claims 1, 17 and 31) and "an exercise activity level" (claim 1), "patient exercise level" (claim 17) and "patient exercise activity level" sensor.

Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

8/19/04

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700